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T. Plunkett
3-11-96
Patent

Attorney's Docket No. 012712-155

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of

Darrell R. ANDERSON et al

Application No.: 08/476,275

Filed: June 7, 1995

For: THERAPEUTIC APPLICATION OF
CHIMERIC AND RADIOLABELED
ANTIBODIES TO HUMAN B LYMPHO-
CYTE RESTRICTED DIFFERENTIA-
TION ANTIGEN FOR TREATMENT
OF B-CELL LYMPHOMA

Group Art Unit: 1816

Examiner: R. Schwadron

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GROUP 1800

SUBMISSION OF DECLARATION PURSUANT TO 37 C.F.R. §1.132

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

This Declaration is being submitted because of an error noted in a sequence in Figure 2D. The Examiner is respectfully advised that upon the Examiner's consideration of the Declaration and his determination that the sequence correction does not constitute new matter, a revised sequence and corrected Figure 2D submission will be submitted to the Patent Office.

If the Examiner has any questions concerning this Declaration, he is respectfully requested to contact the undersigned.

Respectfully submitted,

BURNS, DOANE, SWECKER & MATHIS, LLP

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Date: January 4, 1996



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LYMPHOCYTE RESTRICTED)
DIFFERENTIATION ANTIGEN FOR)
TREATMENT OF B CELL LYMPHOMA)

Group Art Unit: 1806

Examiner: Unassigned

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GROUP 1800

DECLARATION PURSUANT TO 37 C.F.R. § 1.132

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

I, Mitchell E. Reff, declare and state as follows:

(1) I am an inventor of the above-identified patent application;

(2) I have substantial expertise in the design of recombinant expression vectors and more specifically vectors for the expression of recombinant antibodies. My curriculum vitae is attached to this Declaration.

(3) I constructed the vectors which are disclosed in the subject application, including TCAE8, which vector was used to express the subject anti-CD20 antibodies.

(4) I carefully reviewed the above-identified application before filing. However, I inadvertently failed to notice an error in Fig. 2D which figure contains part of the nucleic acid sequence of vector TCAE8. This vector is a tandem chimeric

antibody expression vector which is useful for the production of chimeric antibodies, and more specifically the chimeric anti-CD20 antibodies of the present invention.

(5) More particularly, I failed to notice an error in the recitation of the nucleotides between 5991 to 6000 in Fig. 2D. Fig. 2D incorrectly recites that the nucleotides between 5991 to 6000 are CTTCCCGATTC. In fact, the nucleotides between 5991 to 6000 in TCAE8 should have been identified as CTCCGATTC. Thus, Fig. 2D incorrectly contains an additional "T" after nucleotide 5992.

(6) It is my opinion that the error would have been readily apparent to one skilled in the art upon careful review of the application. The error would have been apparent for example because there are 11 nucleotides contained in Fig. 2D which correspond to nucleotides 5991 to 6000 and there should be 10. Thus, it would have been clear to one skilled in the art that there is an extra nucleotide at some point between 5991 to 6000. The actual error, i.e. that there is an additional "T" after position 5992 would have been apparent upon comparison of SEQ ID NO: 1 which is recited at pages 64 to 68 of the specification to the sequence of Fig. 2D. SEQ ID NO:1 and Fig. 2D both contain the nucleic acid sequence corresponding to vector TCAE8. It can be seen from SEQ ID NO: 1 that nucleotides 5991 to 6000 (see page 67 of the specification) are correctly identified as CTCCCC-ATTC whereas in Fig 2D those nucleotides are identified as CTTCC-CCATTC. Therefore, it is my opinion that the specific error in

the sequence contained in Fig. 2D would have been readily apparent to one skilled in the art upon careful review from the as-filed application.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Date: 12/26/95



Mitchell E. Reff, Ph.D.